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No. 06-770

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SUPREME COURT, U.S.

IN THE

Supreme Court of the United States

STATE OF FLORIDA,

Petitioner,

v.

GABRIEL HARDEN, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE FLORIDA SUPREME COURT

BRIEF IN OPPOSITION FOR RESPONDENT GABRIEL HARDEN

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QUESTION PRESENTED

The restated question presented is:

Whether the Supremacy Clause bars states from criminalizing as Medicaid fraud conduct that falls within the safe harbor exceptions to the Federal Anti-Kickback Statute (a provider paying its employees to solicit and transport Medicaid eligible children for dental services) and which, therefore, would not be deemed criminal under federal law?

INTERESTED PARTIES

Additional parties below, co-defendants in the state criminal proceedings, were:

Vonshella Carter

Elsa Cortorreal

Herbert Goss

Flora Johnson

Billy Madison

Edward Polsky

Maria Rodriguez

Bruce Smith

(Co-defendant Victor Rivera pled guilty and was not a party in the court below.) (Pet. App. G, 67a).

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STATEMENT

A. Introduction

Title XIX of the Social Security Act ("the Medicaid Act") requires states that receive federal funding for health care to provide, *inter alia*, routine dental care to the poor. The Act bars Medicaid providers from making payments or "kickbacks" to third parties in exchange for patient referrals. In addition to punishing such payments as felonies, the Act "excludes" from the Medicaid program (and, indeed, from *all* federal health care programs) any provider convicted of a federal or state crime committed in connection with the program. *See* 42 U.S.C. § 1320a-7(a)(1) and (b)(1).

As a counterweight to the breadth of the federal anti-kickback provisions and severity of the sanctions, Congress created nine exceptions to the definition of a "kickback," and authorized the Secretary of the Department of Health and Human Services ("HHS") to create additional "safe harbors." One such exception, 42 U.S.C. § 1320a-7b(3)(B) (Pet. at 4), as well as one of the now twenty-two safe harbors, 42 C.F.R. § 1001.952(i) (Pet. at 6), expressly immunizes the payments a Medicaid provider makes to his own employees from being either prosecuted as "kickbacks" or used as the basis for "exclusion" from the Medicare or Medicaid programs. Furthermore, the Act requires proof that a provider acted "knowingly and willfully" in prosecutions for violations of the "anti-kickback" provisions. *See* 42 U.S.C. § 1320a-7b(b)(1) and (2).

Respondent Gabriel Harden operated a dental clinic in Miami, Florida. Through a staff of paid employees, he solicited Medicaid-eligible patients and provided them with

assistance in traveling to his dental care center for routine dental services. Under its contract with Medicaid, the State of Florida was required to provide these services. Harden accurately billed the services to Medicaid, and the services were, in fact, performed. Florida prosecutors nonetheless levied criminal charges against him and nine co-defendants, under a state anti-kickback statute, FLA. STAT. § 409.920(2)(e) ("the Florida Medicaid Anti-Kickback Law") (*see* Pet. at 4-5), which omitted *all* of the nine federal exceptions and twenty-two safe harbors, while authorizing prosecutions for mere negligence. (*See* Pet. App. 4a). However, the charges were dismissed, a ruling that was upheld by the Florida District Court of Appeal and the Florida Supreme Court, which agreed that the Florida statute was preempted by federal law. The courts below applied well-established precedents of this Court defining the "conflict preemption" doctrine. Moreover, the Florida Supreme Court's decision did not contradict the will of the Florida Legislature. Under a more specific "anti-kickback" statute, FLA. STAT. § 817.505, which was enacted after the Florida Medicaid Anti-Kickback Law and became effective in 1996, the Florida Legislature criminalized "kickbacks" for patient referrals but, in concert with the Federal Anti-Kickback statute and regulations, expressly excluded from prosecution "[a]ny . . . payment practice not prohibited by 42 U.S.C. § 1320a-7b(b) or regulations promulgated thereunder."[1] And, in 2004, in response to the District Court of Appeal decision in this case, the Florida Legislature amended section 409.920(2)(e) to

1. This later enacted statute is consistent with the decision of the Florida Supreme Court and with the enactment of state anti-kickback statutes in 26 other states, many of which passed legislation after the development of the Federal Anti-Kickback Statute "safe harbor" regulations in 1991 to conform to the federal statutory and regulatory scheme. *See* Appendix, *infra*.

permit prosecutions only for "willful" violations, consistent with federal law. (*See* Pet. App. at 4a, and n. 2). Accordingly, the State has overstated the import of the decision below, and the Petition should be denied.

B. The Medicaid Program in Florida

The Medicaid Program is a "cooperative federal-state program" through which Congress provides financial assistance to the states so that they may furnish medical care to the poor. *See Wilder v. Virginia Hosp. Assoc.*, 496 U.S. 498, 503 (1990). Although participation in the program is "voluntary," participating states "must comply with certain requirements imposed by the Act and regulations promulgated by the Secretary of Health and Human Services (Secretary)." *Id.* Florida has elected to participate in the Program and the federal government currently pays close to 60 percent of all Florida expenditures for services administered under the Medicaid Act.

Routine dental care is one of the mandatory services Congress requires states to provide as a condition of receiving federal funds. *See* 42 U.S.C. §§ 1396d(k)(3); 1396d(a)(10); 1396a(a)(43). In addition to requiring states to provide the actual services, the Medicaid Act requires states to "*inform[] all persons in the State* who are under the age of 21 and who have been determined to be eligible for medical assistance . . . *of the availability of [required] services* as described in section 1396d(r) of this title" and the "*arranging for* (directly or through referral to appropriate agencies, organizations, *or individuals*)" all necessary treatment. 42 U.S.C. § 1396a(a)(43) (emphasis supplied).

Despite these requirements, Florida's own statistics reflect that between 1999-2004 more than 75% of Florida's

Medicaid-enrolled children were furnished no dental care whatsoever. *See* Florida Form 416, Federal Centers for Medicare and Medicaid. Indeed, according to a comprehensive 1996 report issued by HHS, Office of Inspector General, no state provided more than 50 percent of the services required by the Medicaid program. *See* OIG Report No. OEI-09-93-00240, April 1, 1996. The Report found several reasons for the lack of responsibility by the states, including that Medicaid-eligible families tended to give dental care a low priority and were "unwilling to wait for appointments or make necessary travel or child care arrangements which increases the likelihood of missed appointments and failure to seek services." *Id.* at 2, 6. In 2005, this history of neglect resulted in a class action lawsuit against the Florida agency in charge of administering the Medicaid program, charging Florida officials with systematically violating the rights of Florida children by refusing to provide mandatory services, specifically including dental services, as well as failing to provide basic outreach and information to the plaintiff class, as required by § 1396a(a)(43). That lawsuit is ongoing. *See Florida Pediatric Society v. Levine*, S.D. Fla. Case No. 05-23037-Civ-Jordan.

C. The Prosecution

Gabriel Harden earned a Bachelor's Degree in Business Administration and Health Care Management from the University of Colorado. He returned to his native Miami and, in 1997, opened Dental Express, Inc., a management company that operated a turnkey dental facility with the latest dental technology and equipment, office space, administrative staff, inventory and supplies, computers, services, marketing, advertising, accounting, taxes, billing and collections services. His goal was to provide a full range of dental care to inner city children.

By early 1998, after contracting with a group of licensed dentists and dental assistants, Harden had begun providing dental services to inner city youth through contracts with Dade County Head Start, approximately 150 day care centers in Dade and Broward Counties, some twenty-two schools, and numerous school boards. Harden transported the necessary dental equipment to the day care centers and schools, and provided basic dental services on site. However, later that same year, the Florida Legislature banned the use of mobile dental units, which had been providing such services in cooperation with school systems around the state (FLA. STAT. § 409.906(1), (6)), and then notified Harden that his portable services fell within the ban. Since Harden could no longer bring the dentists to the children, he sought to bring the children to the dentists. Accordingly, in December 1998, he began employing staff to market his services and transport Medicaid-eligible patients to his facilities.

Two years later, the state of Florida filed criminal charges against Harden and his co-defendants. (Pet. App. N at 98a-113a) (Information) The State did not allege that there was anything fraudulent about the services Harden billed to Medicaid. Rather, the State alleged that the wages Harden paid to his own staff to solicit Medicaid-eligible patients for services later properly billed to Medicaid constituted illegal "kickbacks" under Florida's Medicaid fraud statute, section 409.920(2)(e), Fla. Stat. (*See* Pet. App. N). That statute, among other things, made it unlawful to "knowingly . . . pay . . . any remuneration . . . in return for referring an individual to a person for the furnishing or arranging for the furnishing of any . . . service for which payment may be made . . . under the Medicaid program."

Although modeled after the federal anti-kickback statute, section 409.920(2)(e) failed to exclude from prosecution the payment practices—the nine statutory exceptions and twenty-two regulatory "safe harbors"—that Congress and HHS have deemed lawful under the Federal Anti-Kickback Statute.[2] Moreover, the 2000 version of the Florida statute defined the term "knowingly" in a manner that included merely negligent conduct: "'Knowingly' means done by a person who is aware *or should be aware* of the nature of his or her conduct and that his or her conduct is *substantially certain* to cause the intended result." FLA. STAT. § 409.920(1)(d) (emphasis supplied). However, as noted above, and as acknowledged by Petitioner (Pet. at 14; Pet. App. at 4a), in 2004 the Florida Legislature amended the definition to eliminate the highlighted language and to define "knowingly" as "willfully." Accordingly, Florida's *mens rea* requirement now matches federal law. *See* p. 15 *infra*.[3]

D. THE PREEMPTION LITIGATION

Harden moved to dismiss the Information (Pet. App. H, pp. 76a-85a), arguing that a Medicaid provider's payment of wages to its employees for the "solicitation and transportation" of Medicaid-eligible children "to dental facilities for treatment" was expressly protected by federal statutes and regulations, that apply to the Medicare and

---

2. Indeed, as discussed *infra*, Congress sought, in part, to *encourage* the payment practices covered by the exceptions and safe harbors.

3. Petitioner correctly notes that the amendment does not moot this case. (Pet. at 14). *See* FLA. CONST. art. 10, § 9 ("Repeal or amendment of a criminal statute shall not affect prosecution or punishment for any crime previously committed.").

Medicaid programs, and that the State's attempt to criminally prosecute this federally-protected activity was unconstitutional under the Supremacy Clause. *See* U.S. CONST. art. VI, cl. 2. Although the State conceded that the defendants were scrupulous in treating only Medicaid-eligible patients, it nonetheless argued that the Florida Legislature was free to ban all payments made, even to employees, for the solicitation of patients. Indeed, during a hearing on Harden's motion to dismiss, the State contended that patient solicitation was a crime under state law even if done through conventional forms of advertising:

> MR. COBB: [B]ut the point is, what they're paid to do is to go out and find patients. In other words, these aren't patients that are waiting somewhere to just go pick up and [bring] back, that the doctors have arranged to have waiting. They're going out in the neighborhoods, they are going up to people, finding people. They're going out and finding Medicaid eligible recipients, individually — speaking to them. . . . The remuneration to the patients it's not really the issue here. It's the remuneration to the drivers to do this, all right. And they are only paid, they're paid per capita for each person they go out and find that's Medicaid eligible and bring them in. The method of bringing them in could be any way. Okay, so they're bringing them in by buses, so what.
>
> The transportation is not the issue here.[4] The issue is that they're going out and finding people

4. In the courts below the State argued that a Medicaid provider could pay no wages of any kind to employees, if the purpose for the wages was for the "solicitation" of Medicaid-eligible patients. (Cont'd)

> on an individual basis, right to Medicaid eligible recipient[s]. Are you Medicaid eligible, fine, come with me and they're bringing them in and they're getting paid per head to do that. That is a crime.
>
> THE COURT: *If they were to go out and put a flyer on every door on a block and then somehow arrange to pick up the people that raised their hands, I want to do that, would that be a problem for the State?*
>
> MR. COBB: *If. It might be, yes. If. And if the way they were paid. Were they paid to go out and just hand out flyers, probably not, but if they were paid on a per capita basis for the number of patients that they directly brought in, I think it would be. . . .*

R2-274-275. (emphasis supplied).

As the hearing evolved so did the State's position on what conduct would be considered legal under the Medicaid program. Thus, the State argued that it was legal to solicit Medicaid eligible patients from a location "say a nursing home that has Medicaid patients . . . already there and you solicit that nursing home . . . that is okay . . . [b]ecause you are not really having any impact on the number of people

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(Cont'd)

In this Court, the State has changed its position, arguing that the factor that made the payments abusive was that the employees were supplying *transportation* to the patients. (*See* Pet. at 10). But, as previously noted, transportation was a service the State itself was required to provide under the Medicaid Act, but was not doing so, according to a pending class action lawsuit. *See* pp. 3-4, *supra*.

who are potentially eligible for Medicaid that come into the system, you see." (R2-275-276.) However, the State contended that the same type of solicitations would be criminal if the targeted population was not *already* enrolled in the Medicaid program:

> MR. COBB: [I]n other words, those [nursing home] people already exist. They're already an expended [sic] group. You're just getting people who have expanded [sic] groups to come to a particular place. That has been ruled to be okay.[5] What is not okay is to go out and try to find people who aren't already coming in somewhere, grabbing them, and having them come in directly and being paid per head for that. That is exactly the method of payment and that's really is the crux of this whole case. What is in a nutshell what we say is being done wrong here and it violates the law and violates the statute. That is it.

(R2-276).

The trial court granted Harden's motion to dismiss, in a lengthy Order (Pet. App. D, pp. 35a-58a), agreeing that section 409.920(2)(e) was preempted by federal law and, therefore, was unconstitutional as applied under the Supremacy Clause. The court further held that the *mens rea* requirement of section 409.920(1)(d) was preempted by federal law and was also unconstitutional under the Supremacy Clause. (Pet. App. D, pp. 52-53). On appeal, both the Third District Court of Appeal and the Florida Supreme

5. The State has never identified any "ruling" that permits the solicitation of patients already receiving Medicaid benefits while banning the solicitation of new patients.

Court affirmed the trial court's rulings. *See* Pet. App. A (Supreme Court), B (Order denying rehearing), C (Third District Court of Appeal).

REASONS FOR DENYING THE PETITION

The state of Florida seeks review of two distinct aspects of the decision by the Florida Supreme Court. First, it argues that the Florida courts misapplied this Court's Supremacy Clause precedents and that states should be free to ban Medicaid providers from engaging in Medicaid payment practices that Congress and HHS have expressly declared are permissible under the Medicaid program. Second, it argues that the decision misapplied the statutory exception and administrative safe harbor for "employer-employee" payments. According to Petitioner, the only wages that fall within the exception and safe harbor are those paid to *medical* employees who provide services that can *themselves* be billed to Medicaid. *See* Pet. at 5-20. In other words, it is Petitioner's contention that while it would be legal for a dentist to pay a duly licensed medical assistant to clean his patients' teeth (since teeth cleaning is a "covered service"), it would be a criminal "kickback" for the dentist to pay the receptionist who made the appointments (since the receptionist's wages cannot be billed to Medicaid). Neither of the State's arguments warrants this Court's review.

I.

THE FLORIDA SUPREME COURT PROPERLY APPLIED THE "IMPLIED CONFLICT PREEMPTION" DOCTRINE

A. THE "IMPLIED CONFLICT-PREEMPTION" DOCTRINE

The Supremacy Clause of the Constitution provides that the "Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. CONST., art. VI, cl. 2. Since *McCulloch v. Maryland*, 17 U.S. (4 Wheat) 316, 427 (1819), "it has been settled that state law that conflicts with federal law is 'without effect.'" *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (citation omitted). Both federal statutes and regulations can have preemptive effect. *See Fidelity Fed. Sav. & Loan Ass'n v. De la Cuesta*, 458 U.S. 141, 153 (1982) ("[f]ederal regulations have no less preemptive effect than federal statutes").

The Court has recognized three discrete categories of preemption: (1) express preemption, where a federal statute contains "explicit preemptive language;" (2) field preemption, in which the federal regulatory scheme is "so pervasive as to make reasonable the inference that Congress left no room for States to supplement it;" and (3) implied conflict preemption, in which compliance with both federal and state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Gade v. Nat'l Solid Wastes Mgmt. Assoc.*, 505 U.S. 88, 98 (1992) (quotations and citations omitted).

In determining whether state law is preempted by implication, the Court's ultimate task is "to determine whether state regulation is consistent with the structure and purpose" of the federal regulatory scheme "as a whole." *Gade*, 505 U.S. at 98; *accord Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363 (2000); *Dalton v. Little Rock Family Planning Servs.*, 516 U.S. 474, 476 (1996). The touchstone is Congressional intent. *See Gade*, 505 U.S. at 96. Thus, state law will be preempted by implication where, "under the circumstances of th[e] particular case," the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress—whether that 'obstacle' goes by the name of conflicting; contrary to; . . . repugnance; difference; irreconcilability; inconsistency; violation; curtailment; . . . interference, or the like." *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000) (internal quotations omitted).

B. Conflict Preemption and the Medicaid Program

Petitioner contends that the application of conflict-preemption principles to void state statutes affecting the Medicaid program is contrary to congressional intent, and that "no court has previously accorded" the federal anti-kickback statute "preemptive effect." (Pet. at 7). While it may be true that no other court has addressed the preemptive effect of the *anti-kickback* provisions of the Medicaid Act, this Court, in *Dalton v. Little Rock Family Planning Servs.*, 516 U.S. 474, 478 (1996), remanded for the entry of an injunction against the enforcement of a state law relating to abortion services to the extent that it conflicted with the Medicaid Act. Numerous other federal and state courts have likewise held that various state laws were preempted by the

Medicaid Act and its regulations.[6] The State cites no authority to the contrary.

Petitioner's contention that the decision below violated conflict preemption principles rests on a central but false premise. According to Petitioner, the structure and history of the federal scheme contemplates not only state involvement in the prosecution and punishment of conduct that falls *outside* the payment practices permitted under the

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6. *See e.g.*, *Antrican v. Odom*, 290 F.3d 178 (4th Cir. 2002) (applied federal preemption principles to the dentistry requirements of the Medicaid program and holding that North Carolina's plan violated and was preempted by more expansive federal dentistry standards); *Planned Parenthood Affiliates v. Engler*, 73 F.3d 634, 637 (6th Cir. 1996) (holding that a provision of Michigan law was invalid under the Supremacy Clause because it conflicted with the Medicaid Act); *Randall v. Lukhard*, 709 F.2d 257 (4th Cir. 1983) (holding that a Virginia rule was invalid because it conflicted with a provision of the Medicaid Act), *aff'd in part*, 729 F.2d 966 (4th Cir. 1984) (*en banc*), *cert. denied*, 469 U.S. 872 (1984); *Smith v. Travelers Indemnity Co.*, 763 F. Supp. 554, 558 (M.D. Fla. 1989) (because Florida's "collateral source rule permits private automobile liability insurers to become secondary sources of recovery behind Medicare, Florida's collateral source rule obstructs the Congressional purpose" behind the Medicare Act and, therefore, is preempted) (citation omitted); *Olszewski v. Scripps Health*, 30 Cal. 4th 798, 69 P.3d 927 (2003) (holding that federal Medicaid statutes and regulations preempted lien provisions of California plan); *Martin v. State*, 642 N.W.2d 1, 34-36 (Minn. 2002) (Minnesota law allowing the state to assert a subrogation right to personal injury awards preempted by anti-lien provision of federal Medicaid Act because "the federal law prohibits exactly what the state law allows"); *Public Health Trust v. Jackson Mem. Hosp.*, 693 So. 2d 562 (Fla. 3d Dist. Ct. App. 1996) (holding that federal law preempted a Florida regulation that allowed hospitals to hold third parties liable for patient services in excess of the amounts paid by the Medicaid program).

federal anti-kickback statute and regulatory "safe harbors," but also permits states to expand the categories of prohibited conduct to include payment practices that fall squarely *within* the protections of federal law. *See* Pet. at 19-20. However, as demonstrated below, Congress' objective in enacting and amending the federal anti-kickback statute was to establish a uniform system providing certainty for providers about what financial practices were legal. While Congress welcomed state involvement as a partner in investigating and penalizing practices that were forbidden under federal law, Congress never envisioned that states would criminalize practices that Congress and the federal agencies overseeing the Medicare and Medicaid programs have expressly deemed permissible. Such a scheme would create chaos in the medical industry, particularly for providers operating in multiple states. Thus, the Florida Supreme Court correctly reasoned that a Florida statute that sought to do just that stood as an "obstacle" to congressional objectives and improperly prevented the payment of acceptable Medicaid claims.

C. The Employer-Employee Exception and Safe Harbor

Both the Medicare and Medicaid programs are subject to the terms of the federal anti-kickback statute, 42 U.S.C. § 1320a-7b, which prohibits certain conduct and payment of claims therefore. When Congress initially enacted these provisions in 1972, they were much narrower than the present form, as they only prohibited the solicitation or offering of a "kickback, bribe or rebate," and only punished a violation as a misdemeanor. *See* Pub. L. No. 92-603, § 242(b), (c), 86 Stat. 1419 (codified at 42 U.S.C. § 1396h(b)).

In 1977, Congress elevated the penalty to a felony and broadened the scope of the prohibition to include "any

remuneration," but then carved out an express statutory exception for "any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services." Pub. L. 95-142 (Oct. 25, 1977). *See* 42 U.S.C. § 1320a-7b(b)(3). However, by 1980, Congress recognized that the statute was so broad that it created uncertainty for healthcare providers and, accordingly, upgraded the *mens rea* to "knowingly and willfully." The legislative history of the amendment indicates that the intent behind the amendment was to clarify what conduct was criminal and when it could be prosecuted: "The Committee is concerned that criminal penalties may be imposed under current law to an individual whose conduct, *while improper, was inadvertent.* Accordingly, Title VIII clarifies present law *to assure that only persons who knowingly and willfully* engage in the proscribed conduct are to be subject to criminal sanctions." H.R. REP. No. 96-1167, p. 202, *reprinted in* 1980 U.S.C.C.A.N. 5526, 5572 (emphasis supplied).

In 1987, in response to concerns over fraud in federal health care programs, as well as continuing complaints from the health care industry about the overbreadth of the statute, Congress enacted a comprehensive series of amendments. *See* Pub. L. No. 100-93. To address the former concern, Congress expanded the types of offenses that would result in a provider's exclusion from participation in the Medicare or Medicaid program to specifically include convictions under either federal *or state* law "in connection with the delivery of a health care item or service . . . of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct." *See* 42 U.S.C. § 1320a-7(a)(1) and (b)(1).

Congress simultaneously amended the anti-kickback provision, authorizing the Secretary of the Department of Health and Human Resources ("HHS") to promulgate "safe harbors" for permissible financial relationships. In granting HHS the authority to create new exceptions to what would otherwise constitute illegal remunerations or kickbacks, the Senate Report specifically recognized:

> It is the understanding of the [Finance] Committee that the breadth of this statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed. The Committee bill therefore directs the Secretary, in consultation with the Attorney General, to promulgate regulations specifying payment practices [1] that *will not be subject to criminal prosecution* under the new section 1128B(b) *and* [2] that *will not provide a basis for exclusion from participation in Medicare or the State health care programs* under the new section 1128(b)(7).

S. REP. No. 100-109, *reprinted in* 1987 U.S.C.C.A.N. 682, 707-708 (emphasis and numbering supplied).

Not satisfied with only the statutory exception for "employer-employee" payments, in 1991, final rules were promulgated creating a parallel administrative "safe harbor" for employer-employee relationships. The rule, now codified at 42 C.F.R. § 1001.952(i), also not only barred such payments from being "treated as a criminal offense" but also prevented such payments from serving "as the basis for an exclusion." Thus, the safe harbor regulation provides in pertinent part:

§ 1001.952 Exceptions.

> The following payment practices [1] *shall not be treated as a criminal offense* under section 1128B of the Act and [2] *shall not serve as the basis for an exclusion*: .
>
> . . .
>
> (i) Employees. As used in section 1128B of the Act, "remuneration" does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, *for employment in the furnishing of any item or service for which payment may be made in whole or in part* under Medicare, Medicaid or other Federal health care programs. For purposes of paragraph (i) of this section, the term employee has the same meaning as it does for purposes of 26 U.S.C. § 3121(d)(2).

(emphasis and numbering supplied).

The employee "safe harbor" also was intended to be expansive and to give every benefit of the doubt to the employer. As OIG explained in issuing section 1001.952(i) as a final rule for the first time in 1991: "The proposed exception for employees permitted an employer to pay an employee *in whatever manner he or she chose for having that employee assist in the solicitation of program business*. . . ." Final Rule, Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991) (Proposed Safe Harbors) (emphasis supplied). And, the scope of the safe harbors was

to prevent the criminal prosecution of a Medicaid employer for paying wages to its employees by characterizing the wages as unlawful "kickbacks." *See Id.* (General Comments Response No. 1: "If a person participates in an arrangement that fully complies with a given provision, he or she will be assured of not being prosecuted criminally or civilly for the arrangement that is the subject of the provision"); *id.* (Response No. 9: "The clear congressional intent behind the development of these safe harbor provisions is to define innocuous arrangements that should not be prosecuted, including the statutory exceptions").

D. *HARDEN* WAS CORRECTLY DECIDED

1. The Exceptions and Safe Harbors

In support of its contention that Congress intended for state legislatures to have the discretion to criminalize precisely the same payment practices that Congress (in statutory exceptions) and HHS (through twenty-two duly promulgated rues) declared to be lawful, Petitioner relies, not on the language or history of the anti-kickback statute, but on an entirely different statute, 42 U.S.C. § 1396b(q)(3). *See* Pet. at 19. Section 1396b(q)(3) authorizes states to create "medicaid fraud unit[s]" to "prosecute individuals for criminal violations" under state law and/or to refer "suspected criminal violations relating to the program . . . to the appropriate" federal authorities. Petitioner strains to construe a snippet of language in this subsection— encouraging states to utilize "all applicable State laws regarding any and all aspects of fraud in connection with" federal health care programs—as an expression of congressional intent to allow states to enact laws criminalizing conduct that would otherwise satisfy a federal statutory exception or safe harbor.

However, nothing in that language, or in any other federal statute, suggests that Congress intended that states were free to *define* as "fraudulent" the *conduct* that Congress and HHS expressly stated was lawful.

To find *any* expression of such a goal in the legislative history of the anti-kickback statute, Petitioner reaches back over 35 years, citing language from a committee report relating to the 1972 legislation, stating that the anti-kickback penalties "would be in addition to and not in lieu of any other *penalty provisions* of state or federal law." H.R. REP. No. 92-231, 5094 (May 26, 1971). While this language suggests that states were free at the time to impose *penalties* greater than those imposed by federal anti-kickback statute, nothing in the report suggested that Congress intended to allow states to prohibit *conduct* that Congress expressly determined was permitted. Indeed, Congress did not recognize the need for exceptions and administrative safe harbors until nearly twenty years later. *See* p. 14-16 *supra*.

The only direct support for Petitioner's construction of Congressional intent is language from an HHS commentary in response to comments received in connection with additional safe harbors promulgated in 1991. *See* Pet. at 9, 19.[7] However, there is no indication that HHS undertook any sort of preemption analysis when it drafted this response. Additionally, the provisions of the federal anti-kickback statute at issue here, 42 U.S.C. § 1320a-7b, were not promulgated by HHS as rules, but instead were enacted as

7. *See* Medicare & State Health Care Programs: Fraud & Abuse, OIG Anti-Kickback Provisions, Final Rule, 56 Fed. Reg. 35952, 35957 (July 29, 1991) (stating that "conduct that is lawful under federal anti-kickback statute or regulation may still be illegal under State law").

statutes by Congress. Congress' intent was set forth in the Senate Committee Report which, as previously stated, indicates that Congress' objective in requiring safe harbors was to provide certainty to providers by describing specific payment practices that would "not provide the basis" for either "criminal prosecution" or "exclusion" from the program. *See* p. 16 *supra*. The Senate Report plainly takes precedence over any conflicting interpretation of Congressional intent regarding preemption offered by HHS.

Indeed, Petitioner's construction of the federal exceptions and safe harbors directly conflicts with the Senate Report. As previously noted, in 42 U.S.C. § 1320a-7(a)(1) and (b)(1), Congress has mandated that even a successful *state* prosecution of a provider will result in the automatic exclusion of that provider from not only Medicaid but from all federal health care programs. However, the Senate Report expressly stated that freedom from "exclusion" was one of the principal objectives of the 1987 amendments that created the safe harbors. Surely Congress did not intend to protect the payment practices set forth in the safe harbors from being used as the basis for exclusion only if the conduct was prosecuted federally, while *requiring* exclusion if the same conduct was prosecuted under state statutes. On the contrary, allowing states to penalize conduct that Congress and HHS went to so much trouble to protect would stand as an "obstacle" to Congress' stated objectives.

Nor is the Medicaid Act unique in preempting state prosecutions for conduct protected by federal law. In *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 364-65 (2000), the Court held that a state statute penalizing individuals and conduct that Congress explicitly exempted from sanctions was preempted by federal law: "sanctions are drawn not only

to bar what they prohibit but to allow what they permit . . ." *Id.* at 366. The Court recognized that the fact that the statutes were aimed at a common end "hardly neutralizes conflicting means." *Id.* at 365. Likewise, the fact that Florida and federal law are both aimed at preventing fraud does not give Florida the power to criminalize conduct that federal law explicitly permits. *See id.* at 366.

Defining "fraud," especially in connection with the operation of a federally funded program, is *not* "a field which States have traditionally occupied." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001). *Buckman* concluded that a state cause of action seeking damages for injuries allegedly caused by bone screws that had been approved by Food and Drug Administration (FDA), predicated on a "fraud-on-the-FDA" theory, was preempted by federal statutes. The Court reasoned that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' such as to warrant a presumption against finding federal pre-emption of a state-law cause of action." *Buckman*, 531 U.S. at 348 (internal citation omitted). *See also Nathan Kimmel, Inc. v. Dowelanco*, 275 F.3d 1199, 1205 (9th Cir. 2002) (plaintiff's state law tort of intentional interference with prospective business advantage based on a "fraud against the [Environmental Protection Agency]" theory was preempted by standards in the Federal Insecticide, Fungicide, and Rodenticide Act); *cf. McCall v. Pacificare of Cal., Inc.*, 25 Cal. 4th 412, 426, 21 P.3d 1189, 1200, 106 Cal. Rptr. 2d 271 (2001) ("[t]o the extent that the [plaintiff's] complaint alleges fraud on the HCFA, defendants may, on remand, assert it is preempted under the rule in *Buckman*").[8]

8. Numerous courts have held that state law tort claims are preempted by the Medicaid Act, where the claims are based, in whole (Cont'd)

Similarly, the State's construction of the interplay between federal and state law would undermine Congress' stated goal of eliminating "uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed." *See* p. 16, *supra*. This Court has already characterized the Medicaid Act as "among the most intricate ever drafted by Congress" with a "Byzantine construction." *Schweiker v. Gray Panthers*, 453 U.S. 34, 43-44 (1981). Allowing each state legislature to determine the legality of payment practices described by Congress or HHS as legal under the Medicaid program would effectively Balkanize the program into as many as 50 subdivisions with potentially different or conflicting standards.[9] Large multi-state providers, in particular, will not know whether their claims for services will be rejected or subject them to civil or criminal penalties. It strains credulity to suggest that Congress intended to allow states to determine the validity of claims paid by the *federal* government.

(Cont'd)

or in part, on a theory that the torts arose from an improper denial of benefits under the Medicaid Act. *See, e.g., Midland Psych. Assoc., Inc. v. United States*, 145 F.3d 1000 (8th Cir. 1998); *Bodimetric Health Servs. v. Aetna Life & Cas.*, 903 F.2d 480 (7th Cir. 1990); *Marin v. HEW, Health Care Fin.*, 769 F.2d 590 (9th Cir. 1985). *See also Wilson v. Chestnut Hill Healthcare*, Civ. A. No. 99-CV-1468, 2000 U.S. Dist. LEXIS 1440 (E.D. Pa., Feb. 10, 2000) ("courts must discount any 'creative pleading' which may transform Medicare disputes into mere state law claims, and painstakingly determine whether such claims are ultimately Medicare disputes").

9. For example, Petitioner could try to apply Florida's Unfair and Deceptive Trade Practices Act, FLA. STAT. §§ 501.201-501.203 (2003). *Cf. Congress of Cal. Servs. v. Catholic Healthcare West*, 87 Cal. App. 4th 491, 510 (Cal. App. 2d 2001) (holding an unfair business practices claim preempted by Medicare).

Compare Lawrence Co. v. Lead-Deadwood Sch. Dist. No. 40-1, 469 U.S. 256, 270 (1985) (holding a state statute placing additional limits on federal funds disbursed by Congress to local governments was preempted).

Finally, Petitioner contends that the decision below would "call[] into question" the constitutionality of statutes from other states. *See* Pet. at 22. But Petitioner fails to identify a single reported case—other than this one—where a state prosecuted a defendant for conduct falling within a federal exception or safe harbor. This case was an anomaly, and the decision below properly found the prosecution to be impermissible.

2. Negligence vs. Willfulness

The Florida Supreme Court also correctly ruled that the Florida Legislature's initial attempt to dilute the *mens rea* requirement for proving kickback violations—from the federal "willfulness" requirement to a negligence standard—constituted a separate violation of the Supremacy Clause. As previously discussed, Congress' decision to elevate the *mens rea* from "knowledge" to "willfulness" in 1980 was intentional, and guided by policy concerns over the breadth of the federal statute. *See* p. 15, *supra*. At the very least, the term "willfulness" means "that the defendant acted with an evil-meaning mind, that is to say, that he acted with knowledge that his conduct was unlawful." *Bryan v. United States*, 524 U.S. 184, 193 (1998). By criminalizing the "accidental" or "negligent" (*i.e.*, non-willful) payment of allegedly unlawful "remunerations"—under circumstances where the Florida Legislature did not even attempt to define the operative term "remuneration" to exclude conduct that is lawful under federal law—section 409.920(2)(e), as

originally enacted, stood as an "obstacle" to the achievement of Congress' stated objectives. *Cf. Fireman's Fund Ins. Co. v. City of Lodi*, 302 F.3d 928 (9th Cir. 2002) (holding invalid under the Supremacy Clause a City ordinance that required companies suspected of committing hazardous waste contamination to prove by "clear and convincing evidence" that others were responsible for the contamination, rather than by a preponderance of the evidence, as required by federal law, 42 U.S.C. §§ 9601-9675), *cert. denied*, 538 U.S. 961 (2003); *Lukhard*, 709 F.2d at 267 (holding that Virginia's burden of proof provisions in its transfer of assets rule under the Medicaid Act were invalid in light of less restrictive federal requirements), *modified in part*, 729 F.2d 966 (4th Cir. 1984) (*en banc*) (construing Virginia's burden of proof provision so as not to conflict with federal standard).

In any event, the Florida Legislature amended the statute in 2004, eliminating the discrepancy between state and federal standards. Accordingly, this issue—although not jurisdictionally "moot" as to the Respondents' case—is no longer a controversy in Florida and, therefore, does not present a sufficiently concrete dispute to warrant granting the Petition. *See Sanks v. Georgia*, 401 U.S. 144 (1971) (dismissing appeal after oral argument because new factual and legal developments, including new state legislation, made it inappropriate to decide the original issue); *Bryan v. Moore*, 528 U.S. 1133 (2000) (dismissing a writ of certiorari as improvidently granted due to intervening amendments by the Florida Legislature to death penalty statute at issue).

II.

CONGRESS DID NOT INTEND TO CRIMINALIZE MARKETING, ADVERTISING OR ASSISTANCE GIVEN TO MEDICAID-ELIGIBLE PATIENTS TO RECEIVE MEDICAL SERVICES THAT STATES ARE REQUIRED TO PROVIDE UNDER FEDERAL LAW

While Petitioner contends that the Florida Supreme Court misapplied the Supremacy Clause by engrafting the federal "employer-employee" exception and safe harbor onto section 409.920, the Petition primarily focuses on the exception and safe harbor. According to Petitioner, the wages a Medicaid provider pays to its employees are protected from prosecution as kickbacks *only* if the employees are medical personnel—presumably the doctors, dentists, nurses and licensed technicians—who are being paid to dispense services that can *themselves* be billed to Medicaid. For example, under the State's construction of the exception and safe harbor, while it is lawful for a provider to pay a dental technician to x-ray and clean a child's teeth, it is a crime for the dentist to pay a receptionist to telephone the child's parents to schedule the next appointment, since Medicaid will not reimburse the provider for the time expended in "soliciting" the patient. Indeed, under Petitioner's proposed construction, all forms of marketing would be illegal. In addition to its absurdity, there are numerous flaws in the State's argument.

First, Petitioner's construction is not compelled by the plain meaning of the employer-employee safe harbor language. Title 42 C.F.R. section 1001.952 immunizes payments for all those "employ[ed] *in the furnishing of* any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs." (emphasis supplied) Any *bona fide* employee of

a dental practice is "employed" in the "furnishing" of services, whether the employee is a dentist, a dental assistant, bookkeeper, receptionist or advertiser.

Second, the only case Petitioner cites in support of its construction, *United States v. Starks*, 157 F.3d 833 (11th Cir. 1998) (Pet. at 17-18), is inapposite. In *Starks*, a corporation that operated a drug treatment program gave kickbacks (essentially bribes) to two employees of the State of Florida Department of Health and Rehabilitation Services ("HRS") to refer patients to the corporation. 157 F.3d at 835-836. The defendants argued that the federal anti-kickback statute was unconstitutionally vague, claiming that "ordinary people in their position might reasonably have thought" that the two HRS "employees" qualified for the statutory exception and safe harbor for employer-employee relationships. *Id.* at 839. The Eleventh Circuit soundly rejected this argument for the obvious reason that the recipients of the kickbacks were not *bona fide* employees of the corporation, but rather were government HRS employees. *Id.* In dicta, the Eleventh Circuit added that the defendants also provided no "covered items" or "legitimate service for which the Hospital received any Medicare reimbursement." *Id.* This dictum, however, cannot be divorced from the principal holding (that the defendants were not corporate employees) or the facts of the case—the defendants were corrupt government HRS workers misusing their public offices for private gain. Nothing of the sort took place here.

Third, if the Court were to adopt the State's radical construction, then *all* forms of Medicaid marketing would be criminalized, from the "flyers" discussed during the trial court oral argument, to television or internet advertising. However, not a whiff of such a purpose can be found in either

the Act's legislative history or HHS commentary. Indeed, the Act itself contemplates outreach to "inform" the eligible population of the "availability" of basic services and the "arranging" of treatment. *See* 42 U.S.C. § 1396a(a)(43). In light of the serious First Amendment ramifications of criminalizing ordinary marketing for medical services, the Court should not assume that Congress intended that anomalous result.

Fourth, the Petition addresses the method of payment by a provider, contending that a Medicaid employer may perhaps pay *salaries* to employees but that *commission*-based wages are illegal. While Congress or HHS could arguably create such a distinction, to date neither has chosen to do so. All Petitioner can point to for the creation of this distinction is an "advisory" opinion—not a duly promulgated rule—issued by HHS in 1996. *See* Pet. at 10. The criminal charges at issue in this case require far more notice than that under the Due Process Clauses of the Fifth and Fourteenth Amendments. Indeed, it was for that reason that the trial court in this case also ruled that section 409.920 was unconstitutional as applied. *See* Pet. App. D, pp. 56a-57a. Moreover, what scarce precedent exists in this area contradicts the State's argument.

For example, in *United States ex rel. Obert-Hong v. Advocate Health Care*, 211 F. Supp. 2d 1045 (N.D. Ill. 2002), the court dismissed a *qui tam* fraud action brought against a hospital. The hospital had entered into contracts with doctors, whereby the hospital would purchase the doctors' practices, transform the doctors into hospital employees and, in return, require the doctors to refer patients to the hospital as a condition of their employment. The opinion makes clear that the amounts paid to the doctors under the employment aspect of the contracts were expressly based on "a percentage of fees collected for referred patients." 211 F. Supp. at 1047. The doctors were paid

on a commission basis, similar to the manner in which Harden paid the drivers in this case. *See also New Boston Gen. Hosp., Inc. v. Texas Workforce Comm.*, 47 S.W.3d 34 (Tex. App. 2001) (contract between hospitals and recruiter was not voidable as in violation of the anti-kickback provision of the Medicaid Act because the recruiter was an "employee" under "safe harbor" provisions of the Act). The decision below properly relied upon *Obert-Hong* and *New Boston General* in concluding that there, as here, payments to *bona fide employees* were within the federal safe harbor, and therefore legal. *See* Pet. App. A, p. 23a.

CONCLUSION

The decision below correctly held that the Florida anti-kickback statute is preempted by the Federal Anti-Kickback Statute and corresponding regulatory exceptions, barring respondents' prosecution. The decision does not conflict with this Court's precedents, and the fact that the Florida statute has been amended to comport with federal law eliminates any future uncertainty about the preemption question. For the foregoing reasons, the petition for writ of certiorari should be denied.

Respectfully submitted,

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APPENDIX

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ALA. CODE § 22-1-11; ARIZ. REV. STAT. § 13-3713; ARK. CODE ANN. §§ 5-55-111, 20-77-902; CAL. WEL. & INST. CODE § 14107.2; COLO. REV. STAT. § 25.5-4-305; CONN. GEN. STAT. § 53a-161c; DEL. CODE ANN. tit. 31, § 1005; 305 ILL. COMP. STAT. § 5/8A-3; KAN. STAT. ANN. § 21-3847; KY. REV. STAT. ANN. §§ 216.2950, 205.8461; LA. REV. STAT. ANN. §§ 14:70.5, 46:438.2; MASS. GEN LAWS ch. 118E, § 41; MINN. STAT. § 62J.23; MO. REV. STAT. §§ 191.905, 198.151, 376.823; MONT. CODE ANN. § 45-6-313; NEV. REV. STAT. § 422.560; N.J. STAT. ANN. § 30:4D-17; N.M. STAT. ANN. §§ 30-41-1–3, 30-44-7; N.Y. SOC. SERV. §§ 366-d, 366-f; OKLA. STAT. tit. 56, § 1005 & OKLA. STAT. tit. 63 § 1-742; R.I. GEN. LAWS §§ 5-48.1-3, 40-8.2-3; S.D. CODIFIED LAWS § 22-45-4; TEX. HUM. RES. CODE § 32.039; VA. CODE ANN. § 32.1-315; WASH. REV. CODE § 74.09.240; WIS. STAT. § 49.49. The states who acted in a similar fashion as the State of Florida (See FLA. STAT. § 817.505), thereby adopting the federal statutory and regulatory exceptions under the Federal Anti-Kickback Statute, include Arkansas, Connecticut, Kentucky, Missouri, Montana, New York, Oklahoma, Rhode Island, Texas, and Virginia. ARK. CODE ANN. §§ 5-55-111, 20-77-902; CONN. GEN. STAT. § 53a -161c; KY. REV. STAT. ANN. §§ 216.2950, 205.8461; MO. REV. STAT. §§ 191.905, 198.151, 376.823; MONT. CODE ANN. § 45-6-313; N.Y. SOC. SERV. §§ 366-d, 366-f; OKLA. STAT. tit. 56, § 1005 & OKLA. STAT. tit. 63 § 1-742; R.I. GEN. LAWS §§ 5-48.1-3, 40-8.2-3; TEX. HUM. RES. CODE § 32.039; VA. CODE ANN. § 32.1-315. Of the remaining states, 12 have enacted anti-kickback statutes with no exceptions (D.C. CODE ANN. § 4-802; FLA. STAT. § 409.920; IND. CODE § 12-17.6-6-12; MD. CODE ANN., CRIM. LAW § 8-511; MICH. COMP. LAWS § 400.604; MISS. CODE ANN. § 43-13-207; N.H. REV. STAT. ANN. § 167:61-a; OHIO REV. CODE ANN. § 2913.40;

PA. STAT. ANN. tit. 62, § 1407; S.C. CODE ANN. § 44-113-60; UTAH CODE ANN. § 26-20-4; W. VA. CODE § 9-7-5), and 13 have never enacted any such statute. Furthermore, Petitioner states that "two states, Missouri and New Mexico, have a mix of laws with and without safe harbors" (Pet. at 22); however, this is inaccurate. Missouri has enacted three anti-kickback statutes which all have "safe harbor" exceptions, and New Mexico has enacted three anti-kickback statutes two of which have "safe harbor" exceptions. MO. REV. STAT. §§ 191.905, 198.151, 376.823; N.M. STAT. ANN. §§ 30-41-1–3, 30-44-7.